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SHADOW ZONES: TRANSPARENCY AND PESTICIDES REGULATION IN THE EUROPEAN UNION

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Abstract

In recent years, pesticides have captured the attention of both policy-makers and the general public. A particular focus has been the transparency of the EU-level procedure for approving active substances, spurred by controversies surrounding the active substance glyphosate. Active substances are the ingredient in pesticides with the pesticidal effect. Once an active substance is approved at EU level, the pesticide containing that active substance must be authorised by each Member State. For this purpose, the EU's 2009 Plant Protection Product Regulation divides Member States into three zones – Northern, Central and Southern – within which, zonal rapporteur Member States evaluate applications for authorisation. National authorisation decisions are based on these zonal evaluations. This novel system governing pesticides is under-researched. Furthermore, unlike active substance approval, the transparency of pesticide authorisation escapes public and policy scrutiny. Drawing on empirical research conducted for the European Parliament, this article evaluates the transparency of the zonal pesticide authorisation procedure. It thus contributes to the literature on transparency a detailed exploration of transparency in a highly complex, decentred and polycentric risk regulation regime. While it finds that the zonal pesticide authorisation procedure, generally speaking, does not operate transparently, it argues further that levels of transparency within the regime as a whole may vary significantly depending on multiple different factors. It introduces the concept of 'chiaroscuro regulation' to characterise and understand these varying levels of transparency across different elements of the regime and considers some of its implications.

Keywords: transparency, pesticides, risk regulation, regulation, governance, European Union

I. INTRODUCTION

Pesticides frequently hit headlines. Controversies over the safety of glyphosate and neonicotinoids represent the two highest-profile examples.¹ While these controversies shine valuable light on certain elements of EU pesticides regulation, other elements operate largely in darkness, escaping the glare of public, and academic, scrutiny. My aim here is to chase some of the shadows from these elements. The article originates in research conducted for a European Implementation Assessment

* I am grateful to Dr Steven Vaughan and Prof Cosmo Graham for their comments on earlier drafts of this article. I presented parts of this research at the 2018 LSA annual meeting in Toronto and the 2018 SLS annual conference in London. My thanks to the participants for their thoughts. I am also grateful to the editors and anonymous reviewer for their helpful comments. Any mistakes are my own.

¹ See, for example, Claire Stam, 'Glyphosate has adverse health effects from doses considered safe, study shows' (17 May 2018) <https://www.euractiv.com/section/agriculture-food/news/glyphosate-has-adverse-health-effects-from-doses-considered-safe-study-shows/>; Sarantis Michalopoulos, 'Environmentalists clash with EFSA over neonicotinoids ban 'exceptions'' (9 August 2018) <https://www.euractiv.com/section/agriculture-food/news/environmentalists-clash-with-efsa-over-neonicotinoids-ban-exceptions/>.

(EIA) of the EU's 2009 Plant Protection Product Regulation ('the Regulation' or 'PPPR').² The EIA involved an in-depth empirical exploration of many aspects of the Regulation.³ This article, however, focuses on one aspect: the transparency of the authorisation procedure for plant protection products.⁴ As described below, longstanding concern over the transparency of pesticides regulation has intensified due to recent controversies, prompting or coinciding with developments in law and policy on pesticides and beyond, on the food chain generally.⁵ This represents an ideal moment to explore transparency in the EU and especially in the context of a regime home to much of the activity. While welcome, this activity is not beyond criticism. The vast majority of developments concentrate on improving transparency only in certain parts of pesticides regulation, discussed further below. This energetic, but limited, focus overshadows other parts of the regime equally deserving of attention, as explored throughout this article.

Before proceeding, a note on terminology is warranted. For simplicity, in the following, I use the generic term 'pesticides' to refer to 'plant protection products'. Pesticides are preparations – herbicides, insecticides, fungicides etc – applied to plants, seeds or plant products to protect them against harmful organisms.⁶ Pesticides contain one or more active substances; these are the ingredients with pesticidal effect. For example, glyphosate is an active substance and 'Round-Up' is a pesticide which contains glyphosate.

The Regulation is discussed in Parts III and IV. For now, it suffices to say that it implements a dual assessment system for pesticides and their active substances. This involves, firstly, an EU level procedure for evaluating and approving active substances. Though the vast majority of public and policy scrutiny centres on this procedure, active substance approval is not the full pesticide regulatory story. The Regulation also divides Member States (and Norway) into three zones with comparable 'agricultural, plant health and environmental (including climatic) conditions' – Northern, Central and Southern, for the purposes of evaluating and authorising pesticides.⁷ In essence, applications for authorisation are evaluated at a 'zonal' level by a 'zonal rapporteur Member State' whose conclusions provide the basis for final, national authorisation decisions in that zone.

The zonal pesticide authorisation procedure sparks little public interest and, despite the high, and controversial, public profile of active substance approval, pesticides regulation generally eludes the academic spotlight, although the EIA made a significant grab. Other contributions to the EIA and the only major work on the Regulation came from political science.⁸ Although this work engages with the law, legal academia itself throws little light on pesticides regulation.⁹ This is unfortunate because pesticides regulation generally, and the uniqueness of the Regulation's

² Regulation (EC) No 1107/2009 [2009] OJ L309/1.

³ A Dinu, E Karamfilova and Ex-Post Evaluation Unit, *Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market: European Implementation Assessment* (2018).

⁴ I do, however, incorporate some empirical insights from my contribution to the EIA, O Hamlyn, 'Assessing Member States' Capacity for Reliable "Authorisation of PPPs", and Its Uniformity' (Ex-Post Evaluation Unit, 2018), to supplement the discussion. The empirical research for that report involved the distribution of a survey to Member State competent authorities (CAs) containing quantitative and qualitative questions regarding, inter alia, the transparency of their procedures and practice. For a detailed methodology, see *ibid* 40–50.

⁵ Discussed further in Part III.

⁶ The technical term 'plant protection products', used in the Regulation, in fact also refers to other types of preparations, such as plant growth regulators and pest repellents.

⁷ PPPR, Recital 29, Art 3(17), Annex I.

⁸ E Bozzini, *Pesticide Policy and Politics in the European Union* (Springer International Publishing, 2017).

⁹ Exceptions include O Hamlyn, 'Sustainability and the Failure of Ambition in European Pesticides Regulation' (2015) 27 *Journal of Environmental Law* 405, which discusses the Regulation's sister Directive, Directive (EC) 2009/128 [2009] OJ L309/71, and GC Leonelli, 'The Glyphosate Saga and the Fading Democratic Legitimacy of European Union Risk Regulation' (2018) 25(5) *Maastricht Journal of European and Comparative Law* 582.

pesticide authorisation procedure specifically, offer fertile ground for research, not only within the environmental law specialism but also with respect to EU regulation and governance generally. The regime established by the Regulation is characterised by the inter-play of different actors at different levels of governance – EU, national, as well as ‘zonal’ – and requires Member State competent authorities (CAs) to work together on the highly technical (in both scientific and legal terms) matters of evaluating and regulating the risks posed by pesticides and their ingredients. Furthermore, tensions between, for example, the public interest in safety and transparency and commercial/industrial interests in confidentiality and ensuring the availability of pesticides can result in these matters of evaluation and regulation becoming highly politicised. For these (and other) reasons, EU pesticides regulation presents openings to explore and further develop theory regarding, for example, risk regulation, decentred/polycentric regulation and the operation of regulatory agencies or networked, collaborative or multi-level governance. For now, the article seeks firstly, to understand and evaluate the level(s) of transparency achieved by the Regulation. Secondly, it uses this analysis to offer a more general observation about transparency in a highly complex, polycentric risk regulation regime.

The article is structured as follows. Part II discusses transparency as a principle of governance. First, it contextualises transparency in the regulatory reforms sweeping Europe since the mid-1970s. Secondly, it presents a normative understanding of transparency in the context of a highly technical and complex, risk-based regulatory regime. Implementing transparency may depend on myriad requirements. The analysis in this article takes it as consisting of clarity with regard to the rules of the game, access to information and wider stakeholder and public participation in decision-making. Part III first discusses the policy behind the Regulation and secondly, explores briefly the active substance approval procedure and recent transparency-related policy and legislative developments relating to that procedure. Part IV is the core of the article. Part IV A presents a description of the pesticide authorisation procedure and evaluates the transparency of this procedure against the three requirements defined in Part II. Part IV B highlights the importance of transparency in pesticide authorisation as well as active substance approval.

Part V advances two arguments. Working from the analysis in Part IV, I argue that the zonal pesticide authorisation procedure, generally speaking, does not operate transparently. However, the transparency-focused analysis of the Regulation provides the basis for a second, more nuanced argument. I argue that levels of transparency within the regime established by the Regulation as a whole may vary significantly depending on multiple different factors. These factors include national regulator practice, actor, level of decision-making procedure (EU, zonal, national) and regulatory object. It is, as a consequence, impossible to draw universal and fixed conclusions about the transparency of regulatory actors and procedures in the context of such a complex, polycentric and continuously evolving regulatory regime. The result is a regime typified by varying shades of illumination and inumbration across its different elements, all with the potential to fluctuate; a phenomenon I define as ‘chiaroscuro regulation’.¹⁰ I use this concept to describe and encapsulate characteristics of this regime and its levels of transparency, as revealed by the analysis in this Part. These characteristics include the sharp contrasts in transparency within the regime, the relevance of the audience when discussing transparency and the significance of the gradual nature of developments in transparency. As a descriptive concept, it aims to epitomise and thereby aid understanding of the nature of transparency in complex regimes. Part V closes with consideration of some of the consequences of chiaroscuro regulation. Part VI concludes by highlighting the

¹⁰ ‘Chiaroscuro’ is an Italian term which literally means ‘light-dark’. It is traditionally used to describe dramatic tonal contrasts in the visual arts, primarily paintings.

contingency of transparency, in practice, on those factors identified and the potential implications for democratic accountability and the quality of decisions.

II. TRANSPARENCY IN CONTEXT

Transparency is complex and, unlike pesticides regulation, increasingly elucidated by a rich and growing literature.¹¹ Much of this literature is theoretical. It concerns reasons for and against transparency and measures for achieving transparency,¹² often situated in the broader context of regulatory reform across Europe since the mid-1970s. Briefly, this reform was characterised by, *inter alia*, increasing delegation of regulatory powers to independent regulatory authorities at national and supranational levels.¹³ This ‘agencification’, while affecting mainly economic regulation, also touched social regulation, which encompasses the fields of, *inter alia*, pharmaceuticals, food safety and environmental regulation,¹⁴ and therefore pesticides regulation. Independence from elected officials, and therefore traditional methods of accountability, prompted concerns.¹⁵ The public cannot hold an authority to account unless its activities are first made visible.¹⁶ Thus transparency, being associated with making the exercise of power accessible or visible,¹⁷ became a crucial tool for ensuring accountability. Increased transparency has also been a response to the secrecy and opacity associated with previous regulatory styles and scandals.¹⁸ For example, transparency was central to post-BSE food safety regulation reform,¹⁹ and the constitution of both the European Food Safety Authority (EFSA) and the UK’s Food Standards Agency.²⁰ Improving the transparency of regulatory science was at the heart of EU reforms aimed at raising public confidence its law and policy on food safety at the turn of the century.²¹

These developments in regulation have coincided with a diversification of regulatory arenas, leading to the decentring and polycentricity of regulatory authority, increasingly scattered across multiple interdependent or networked, state and non-state actors in multiple sub-national, national

¹¹ A good starting point is C Hood and D Heald (eds), *Transparency: The Key to Better Governance?* (Oxford University Press, 2006).

¹² See contributions to Hood and Heald, note 11 above.

¹³ G Majone (ed), *Regulating Europe* (Routledge, 1996), pp 3, 10–11, 47–48.

¹⁴ F Gilardi, ‘The Institutional Foundations of Regulatory Capitalism: The Diffusion of Independent Regulatory Agencies in Western Europe’ (2005) 598 *The ANNALS of the American Academy of Political and Social Science* 84, p 85.

¹⁵ M Thatcher, ‘Delegation to Independent Regulatory Agencies: Pressures, Functions and Contextual Mediation’ (2002) 25 *West European Politics* 125, p 141; M Everson, ‘Independent Agencies: Hierarchy Beaters?’ (1995) 1 *European Law Journal* 180.

¹⁶ E Vos, ‘Independence, Accountability and Transparency of European Regulatory Agencies’ in D Geradin, R Muñoz and N Petit (eds), *Regulation through Agencies in the EU: A New Paradigm of European Governance* (Edward Elgar, 2005), p 129.

¹⁷ E Fisher, ‘Transparency and Administrative Law: A Critical Evaluation’ (2010) 63 *Current Legal Problems* 272, pp 277, 283.

¹⁸ E Vos, ‘EU Food Safety Regulation in the Aftermath of the BSE Crisis’ (2000) 23 *Journal of Consumer Policy* 227, p 246; Thatcher, note 15 above, p 142; L Hellebø Rykkja, ‘Independent Food Agencies – Restoring Confidence’ (2004) 23 *Policy and Society* 125, p 129; R Löfstedt, ‘Risk Communication and Management in the Twenty-First Century’ (2004) 7 *International Public Management Journal* 335, p 340.

¹⁹ Hellebø Rykkja, note 18 above; Vos, note 18 above.

²⁰ Fisher, note 17 above, pp 299–300; J Krebs, ‘Establishing a Single, Independent Food Standards Agency: The United Kingdom’s Experience’ (2004) 59 *Food and Drug Law Journal* 387.

²¹ Regulation (EC) No 178/2002 [2002] OJ L31/1 (General Food Law), Recital 18; Commission, ‘White Paper on Food Safety COM(1999) 719 Final’; J Scott and E Vos, ‘The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle within the EU and the WTO’ in C Joerges and R Dehousse (eds), *Good Governance in Europe’s Integrated Market* (Oxford University Press, 2002), pp 282–283.

and transnational locations.²² Challenges include identifying the responsible institution in a progressively complex institutional landscape. With respect to independent regulators, a separate, independent identity has been argued to enhance transparency and openness,²³ promoting visibility and control and accountability to dense networks of actors extending beyond the state.²⁴ Other challenges include the blurring of the boundaries between expert advice and policy,²⁵ and between public and private.²⁶ Dispersal of regulatory responsibility or the pooling of information on risks from different sources may be exploited to institutionalise ambiguity and thereby avoid allocation of blame or liability simultaneously impeding the ability of citizens to understand the regime,²⁷ although ambiguity around authority can also have positive or productive consequences.²⁸ One important hallmark of decentred regulation, for this article, is the fragmentation of knowledge. Beyond the familiar potential for information asymmetry between regulator and regulatee, within this 'regulatory space', resources, including regulatory authority, 'information, wealth and organisational capacities' and the knowledge and oversight necessary for problem-solving and effective regulation are dispersed across different state and non-state organisations, rather than monopolised by a hierarchical state.²⁹ These combined developments intensify problems of accountability.³⁰ They have also prompted calls for greater transparency.³¹

Transparency is not a transcendent principle; its meaning and purpose vary depending on context.³² However, scholarship reveals certain norms which transparency may often encompass. It is possible therefore, drawing on literature on transparency, relevant EU law and policy and by reference to the specific characteristics of pesticides regulatory regime, to identify requirements for transparency in the context of this, and perhaps other, complex, transnational risk regulation regimes. This article takes transparency as consisting of three requirements. It is against these requirements that I evaluate the transparency of the Regulation in Part IV A. Firstly, clarity with regard to the rules of the game. Extending transparency to the 'rules, data and informational requirements ... used to make decisions' is argued to build confidence in the regulator amongst publics and the regulated industry.³³ The Regulation establishes complex procedures which operate

²² J Black, 'Decentring Regulation: Understanding the Role of Regulation and Self-Regulation in a "Post-Regulatory" World' (2001) 54 *Current Legal Problems* 103, pp 105-112; J Black, 'Constructing and Contesting Legitimacy and Accountability in Polycentric Regulatory Regimes' (2008) 2 *Regulation & Governance* 137, pp 139-140.

²³ Vos, note 18 above.

²⁴ Vos, note 16 above, p 125; C Scott, 'Accountability in the Regulatory State' (2000) 27 *Journal of Law and Society* 38.

²⁵ Vos, note 16 above, p 121; M Shapiro, 'The Problems of Independent Agencies in the United States and the European Union' (1997) 4 *Journal of European Public Policy* 276.

²⁶ C Scott, 'Regulation in the Age of Governance: The Rise of the Post Regulatory State' in J Jordana and D Levi-Faur (eds), *The Politics of Regulation* (Edward Elgar, 2004), pp 146-147.

²⁷ C Hood, H Rothstein and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press, 2001), pp 128-129, 164-169.

²⁸ M Lee, 'The Ambiguity of Multi-Level Governance and (De-)Harmonisation in EU Environmental Law' (2013) 15 *Cambridge Yearbook of European Legal Studies* 357.

²⁹ L Hancher and M Moran, 'Organizing Regulatory Space' in R Baldwin, C Scott and C Hood (eds), *A Reader on Regulation* (Oxford University Press, 1998), pp 159-160, 163-165; C Scott, 'Analysing Regulatory Space: Fragmented Resources and Institutional Design' (2001) *Public Law* 329, pp 330-331, 334-338; Black, 'Decentring Regulation', note 22 above, p 107.

³⁰ Black, 'Constructing', note 22 above, p 141.

³¹ M Lodge and L Stirton, 'Accountability in the Regulatory State' in R Baldwin, M Cave and M Lodge (eds), *The Oxford Handbook of Regulation* (Oxford University Press, 2010), pp 355, 359.

³² Fisher, note 17 above, pp 277, 283.

³³ OECD, *Principles for the Governance of Regulators: Public Consultation Draft* (OECD 2013), pp 51-52.

differently across Member States.³⁴ Clear descriptions of these procedures and how they operate in the national context would facilitate understanding as well as the involvement of stakeholders and civil society, the third requirement, discussed below.

Secondly, access to information. Narrow definitions of transparency would refer to ‘minimal openness of process, access to documents and, publication of official measures’.³⁵ A requirement, for example, that public authorities give reasons for their decisions activates accountability mechanisms, including judicial review, allowing citizens to defend their rights and the courts to exercise their supervisory functions as well as supporting public participation.³⁶ It may also encourage decision-makers to balance the pros and cons of a decision more than those whose reasoning remains unlit, thereby helping to control discretion.³⁷ Some argue that openness, transparency and honesty, generally, increase trust or confidence in organisations, while secrecy destroys it.³⁸ Such trust may, furthermore, support a regulator’s legitimacy.³⁹ The EU endorses many of the claims made of transparency. For example, the Court of Justice of the EU (CJEU) and EU legislation have supported public access to information for, *inter alia*, its contribution to transparency and democratic accountability.⁴⁰ In addition, Directive (EC) 2003/4 recognises the contribution increased public access to environmental information makes to ‘a greater awareness of environmental matters, a free exchange of views, more effective participation by the public in environmental decision-making and, eventually, to a better environment’.⁴¹ Despite these benefits, there are potential drawbacks to enhancing transparency, suggesting the need for care in promoting access to information. Transparency may in fact decrease trust and cause harm.⁴² For example, it could encourage members of the public to make their own decisions about risks, instead of relying on expert regulators.⁴³ Publishing unfiltered scientific findings could cause public alarm with drastic public health consequences.⁴⁴ Furthermore, transparency may precipitate disagreement disruptive of the bases and procedures of decision-making.⁴⁵ This may be true especially where, as with pesticides, assessments of risk are already contested.⁴⁶

As discussed in Parts III B and IV A, pesticides regulation is information-heavy. Applicants generate and submit large amounts of information as part of their applications for approval or authorisation and decision-makers rely on this information to make decisions. More specifically,

³⁴ See Part IV A.

³⁵ HCH Hofmann, ‘General Principles of EU Law and EU Administrative Law’ in C Barnard and S Peers (eds), *European Union Law* (Oxford University Press, 2014), p 207.

³⁶ Majone, note 13 above, p 300.

³⁷ M Shapiro, ‘The Giving Reasons Requirement’ (1992) *University of Chicago Legal Forum* 179, pp 180-181.

³⁸ R Löfstedt, *Risk Management in Post-Trust Societies* (Palgrave Macmillan, 2005) p xv; RG Peters, VT Covello and DB McCallum, ‘The Determinants of Trust and Credibility in Environmental Risk Communication: An Empirical Study’ (1997) 17 *Risk Analysis* 43.

³⁹ TR La Porte and DS Metlay, ‘Hazards and Institutional Trustworthiness: Facing a Deficit of Trust’ (1996) 56 *Public Administration Review* 341, p 342.

⁴⁰ S Peers, ‘The EU’s Political Institutions’ in Barnard and Peers, note 35 above, p 69; P Craig and G De Búrca, *EU Law: Text, Cases and Materials*, 6th ed (Oxford University Press, 2015), pp 569-574. See also Regulation (EC) No 1049/2001 [2001] OJ L145/43, Recital 2.

⁴¹ Directive (EC) 2003/4 [2003] OJ L41/26, Recital 1.

⁴² O O’Neill, ‘Transparency and the Ethics of Communication’ in Hood and Heald, note 11 above; Fisher, note 17 above, p 282.

⁴³ Löfstedt, note 18 above, pp 340–341.

⁴⁴ Löfstedt, note 38 above, p xv; see also EESC, ‘Opinion of the European Economic and Social Committee on the Proposal for a Directive of the European Parliament and of the Council Establishing a Framework for Community Action to Achieve a Sustainable Use of Pesticides’ (2007), pp 7-8.

⁴⁵ Fisher, note 17 above, p 305.

⁴⁶ Bozzini, note 8 above, ch 4.

under the Regulation, authorisation decisions are based almost exclusively on scientific evidence, in the form of a risk assessment.⁴⁷ Where scientific knowledge forms the basis of public decisions with significant implications for human health and the environment, as with pesticides, democratic control ‘demands some ability on the part of a polity to evaluate the knowledge claims that justify actions taken on its behalf’.⁴⁸ Public reporting, and therefore the possibility of public scrutiny, of the relevant information may prevent regulators adjusting evidence to suit a policy position.⁴⁹ Finally, improved public understanding of the bases for decisions enabled by transparency, particularly access to information, may ensure more effective participation, the third requirement.⁵⁰

Thirdly, wider stakeholder and public participation in decision-making. Beyond access to information, consultation is central to transparency.⁵¹ It has been argued that full transparency is only achieved through knowledge of decision-making acquired by direct participation.⁵² That said, full transparency through participation may not maintain or enhance trust in a regulator unless the public’s impression of the reliability of its internal operations actually improves as a result.⁵³ Within the EU, the Commission has emphasised ‘effective and transparent consultation’ and a ‘reinforced culture of consultation and dialogue’, recognising the importance of public participation for good governance generally (albeit, there, in the context of policy formation rather than regulatory decision-making).⁵⁴ Recital 3, Directive (EC) 2003/35 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment states that ‘[e]ffective public participation in the taking of decisions enables the public to express, and the decision-maker to take account of, opinions and concerns which may be relevant to those decisions, thereby increasing the accountability and transparency of the decision-making process and contributing to public awareness of environmental issues and support for the decisions taken’.⁵⁵ The Lisbon Treaty acknowledges the link between openness, transparency and participation.⁵⁶ Likewise, the General Food Law conceives transparency as entailing openness and public consultation.⁵⁷

Furthermore, social and ecological uncertainty characterise the contexts of pesticide use.⁵⁸ Assessment of the risks pesticides pose is a highly complex task, presenting challenges for risk assessors and regulators.⁵⁹ For example, the behaviour of farm workers applying pesticides in the field is unpredictable.⁶⁰ So too, are the indirect and cumulative effects of pesticides on whole

⁴⁷ PPPR, Art 36(1).

⁴⁸ S Jasanoff, ‘Transparency in Public Science: Purposes, Reasons, Limits’ (2006) 69 *Law and Contemporary Problems* 21, p 21.

⁴⁹ SE Dudley and K Wegrich, ‘The Role of Transparency in Regulatory Governance: Comparing US and EU Regulatory Systems’ (2016) 19 *Journal of Risk Research* 1141, p 1143, although this presupposes that there exist those with the requisite expertise to perform the scrutiny.

⁵⁰ J Stern and S Holder, ‘Regulatory Governance: Criteria for Assessing the Performance of Regulatory Systems: An Application to Infrastructure Industries in the Developing Countries of Asia’ (1999) 8 *Utilities Policy* 33, p 43.

⁵¹ R Deighton-Smith, ‘Regulatory Transparency in OECD Countries: Overview, Trends and Challenges’ (2004) 63 *Australian Journal of Public Administration* 66, p 67.

⁵² Shapiro, note 37 above, pp 204–205.

⁵³ La Porte and Metlay, note 39 above, p 344.

⁵⁴ Commission, ‘European Governance: A White Paper COM(2001) 428 Final’, pp 15–17.

⁵⁵ Directive (EC) 2003/35 [2003] OJ L156/17.

⁵⁶ Arts 1, 10 and 11(2)–(3) TEU and Art 15(1) TFEU.

⁵⁷ General Food Law, note 21 above, Arts 9, 10, 38.

⁵⁸ B Wynne, ‘Risk and Social Learning: Reification to Engagement’ in S Krinsky and D Golding (eds), *Social Theories of Risk* (Praeger, 1992); J Pretty, ‘Preface’ in J Pretty (ed), *The Pesticide Detox: Towards a More Sustainable Agriculture* (Earthscan, 2005).

⁵⁹ R Baldwin, ‘Regulatory Legitimacy in the European Context: The British Health and Safety Executive’ in Majone, note 13 above, pp 87–88.

⁶⁰ Wynne, note 58 above.

ecosystems.⁶¹ The reporting of expert deliberations, uncertainties, ambiguities and disagreements for example, may open up decision-making and enhance transparency.⁶² Given the often controversial nature of risk-based decision-making and the need for, and inevitability of, assumptions and value judgments in the assessment and management of risk,⁶³ especially in situations of uncertainty, public involvement may benefit decision-making by incorporating citizens' values in the weighing of uncertain benefits against uncertain risks.⁶⁴ The availability of more information and perspectives through wider participation may generate better decisions,⁶⁵ for example where scrutiny enables the identification of errors or contributions aid problem-solving.⁶⁶ Even where improved decisions do not result, participation is regarded as having normative value.⁶⁷ Finally, and in more practical terms, decisions about pesticides affect numerous stakeholders and publics across the EU, who should therefore be granted a voice. Furthermore, recent campaigns demanding greater transparency demonstrate an appetite for increased citizen involvement in these decisions.⁶⁸

In addition to elaborating various requirements of transparency, much of the literature on transparency is punctuated with examples of more or less transparent laws, regulation or regulators and sometimes more extended analyses of the achievement of transparency by a particular legal instrument.⁶⁹ There is, however, less work which presents a sustained exploration of transparency in the context of a single complex, transnational regulatory regime or how transparently such a regime operates in practice. This article's contribution to the literature is such an exploration of transparency.⁷⁰

III. EU PESTICIDES POLICY AND REGULATION: ACTIVE SUBSTANCE APPROVAL AND POLICY DEVELOPMENTS

A. Policy

Pesticides have long been contested. They are valued for their contribution to maintaining crop yields and the production of affordable fruit and vegetables, as well as bolstering the economy more generally. In 2014, for example, the EU market for pesticides was worth almost €10 billion.⁷¹ They also, however, pose risks to human health and the environment and may themselves undermine

⁶¹ J Pretty and R Hine, 'Pesticide Use and the Environment' in Pretty, note 58 above, pp 15-18.

⁶² Andy Stirling, "'Opening Up" and "Closing Down": Power, Participation, and Pluralism in the Social Appraisal of Technology' (2008) 33 *Science, Technology & Human Values* 262.

⁶³ B Wynne, 'Uncertainty and Environmental Learning: Reconceiving Science and Policy in the Preventive Paradigm' (1992) 2 *Global Environmental Change* 111, p 116; M Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Edward Elgar, 2008), pp 41-42.

⁶⁴ J Steele, 'Participation and Deliberation in Environmental Law: Exploring a Problem-solving Approach' (2001) 21 *Oxford Journal of Legal Studies* 415, pp 421-427.

⁶⁵ J Parkins and R Mitchell, 'Public Participation as Public Debate: A Deliberative Turn in Natural Resource Management' (2005) 18 *Society & Natural Resources* 529, pp 531-533.

⁶⁶ M Lee, *EU Environmental Law, Governance and Decision-Making*, 2nd ed (Hart, 2014), p 197; Steele, note 64 above.

⁶⁷ F Schauer, 'Transparency in Three Dimensions' (2011) 2011 *University of Illinois Law Review* 1339, p 1349.

⁶⁸ For example the European Citizens' Initiative 'Stop Glyphosate', discussed in Part III B.

⁶⁹ For example, C Hood, R Baldwin and H Rothstein, 'Assessing the Dangerous Dogs Act: When Does a Regulatory Law Fail?' (2000) *Public Law* 282; Hood, Rothstein and Baldwin, note 27 above.

⁷⁰ While the analysis identifies many deficiencies in terms of the transparency of pesticides regulation and therefore broad scope for reform, it is not my intention here to offer suggestions. Recommendations for reforming the Regulation can be found in Hamlyn, note 4 above, pp 97-101.

⁷¹ EPRS, *EU Policy and Legislation on Pesticides: Plant protection products and biocides* (EUR-OP, 2017), p 6.

crop protection through the elimination of natural predators and increasing pesticide resistance.⁷² The turn of the century witnessed a radical change in EU pesticides policy.⁷³ This led to repeal of the Regulation's predecessor directive ('the Directive').⁷⁴ Reviews of the Directive found its procedures for assessing active substances and pesticides to be inefficient, subject to delays and to encourage duplication of administrative work among Member States.⁷⁵ Bozzini highlights three particular problems with the Directive which hindered fulfilment of the EU's pesticide policy goals. Firstly, the challenges of establishing harmonised data requirements and approval criteria significantly delayed the assessment of active substances already on the market and the implementation, generally, of the Directive. Secondly, those delays perpetuated the existing market fragmentation, improving little on the pre-Directive situation in which common rules were absent. Finally, the delays in assessing active substances in use, alongside scarce and incomplete data, aggravated public health concerns.⁷⁶

Multiple motivations drove the reform, including reinforcing a high level of health and environmental protection, improved functioning of the EU internal market, harmonising availability of pesticides between farmers in different Member States and increasing transparency.⁷⁷ While the Regulation retained the dual assessment system established under the Directive,⁷⁸ it introduced a new zonal system for authorising pesticides, as mentioned in the Introduction and discussed in greater detail in Part IV A. Mutual recognition of pesticide authorisations within zones emerged as a means to achieve the aims of the reform and address the failures of mutual recognition under the Directive.⁷⁹ Overall, the zonal system and the compulsory mutual recognition within zones it would facilitate, sought administrative efficiency through simplifying the authorisation procedure, increasing work-sharing and co-ordination between Member States within zones to avoid unnecessary duplication of work and reduce administrative and financial burdens for industry and Member States, speeding up decision-making and increasing efficiency.⁸⁰ The Regulation's recitals also reflect these aims.⁸¹

In terms of policy on transparency during the reform, efforts to improve transparency in pesticides regulation focused mainly on the procedure for approving active substances rather than pesticide authorisation,⁸² a trend which continues today.⁸³ The transparency of the pesticide authorisation process under the Directive was identified as a problem worthy of attention.⁸⁴ The European Parliament considered 'the greatest possible transparency in licensing and use ... to be

⁷² For more information on benefits and drawbacks of pesticides, see *ibid*, pp 8-10 and Hamlyn, note 9 above, pp 3-6.

⁷³ Bozzini, note 8 above, ch 3.

⁷⁴ Directive (EEC) 91/414 [1991] OJ L230/1.

⁷⁵ Commission, 'Evaluation of the Active Substances of Plant Protection Products COM(2001) 444 Final'; Commission, 'Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products SEC(2006) Final', pp 10-18.

⁷⁶ Bozzini, note 8 above, pp 61-65.

⁷⁷ Commission, 'Proposal for a Regulation of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market COM(2006) 388 Final', pp 2-3.

⁷⁸ Commission, 'Evaluation', note 75 above, p 8.

⁷⁹ Commission, 'Report on the Impact Assessment', note 75 above, p 5.

⁸⁰ Commission, 'Proposal for a Regulation', note 77 above, pp 7, 11-12, 16; Commission, 'Report on the Impact Assessment', note 75 above; Commission, 'Amended Proposal for a Regulation of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market COM(2008) 93 Final', pp 3, 6; Council of the European Union, 'Press Release 9039/08 (Presse 118)', p 6; FCEC, 'Impact Assessment of Options for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products' (2006).

⁸¹ PPPR, Recitals 12, 14, 25 and 29. See also Art 75(3).

⁸² Commission, 'Proposal for a Regulation', note 77 above, pp 9, 14.

⁸³ See Parts III B-IV A.

⁸⁴ FCEC, note 80 above, p 81.

essential'.⁸⁵ It also criticised the system under the Directive for its lack of public access to information.⁸⁶ It sought, therefore, to amend earlier drafts of the Regulation to ensure public access to information regarding applications for pesticide authorisations and to enhance the transparency of its procedures generally.⁸⁷ The zonal system was a compromise between a fully centralised decision-making approach (pesticide authorisation at EU level) and the decentralised system of national authorisations under the Directive.⁸⁸ Policy sheds little explicit light on how the system was conceived, its design or on any balancing of administrative efficiency against other values, such as transparency. Priorities are clear, however, in the iterations of the legislative text: the zonal system survived European Parliament objections that zones are arbitrary and conditions not comparable.⁸⁹ However, European Parliament amendments to enhance transparency survive in either a weakened form or not at all.

B. Active substance approval

Active substances are approved at EU level, with the involvement of EFSA and the Commission, aided by comitology. Manufacturers submit an application, consisting of a complete and summary dossier containing the necessary data requirements,⁹⁰ for approval to a specific 'rapporteur Member State'.⁹¹ Summary dossiers are made available to the public, minus any information deemed confidential pursuant to Article 63.⁹² The rapporteur Member State must conduct 'an independent, objective and transparent assessment in the light of current scientific and technical knowledge' of the information provided to determine 'whether the active substance can be expected to meet the approval criteria' in Article 4.⁹³ These criteria largely relate to the safety and efficacy of the active substance and are discussed further in Part IV B.

The rapporteur Member State produces a 'draft assessment report' which EFSA makes available to the public (minus confidential information), for a 60 day consultation period.⁹⁴ EFSA adopts a conclusion on whether the active substance can be expected to meet the Article 4 criteria and makes it available to the Commission, Member States and the public.⁹⁵ Taking into account the draft assessment report and EFSA's conclusion, the Commission produces a 'review report' and draft regulation, providing for approval, or not, of the active substance, which it submits to the Standing Committee on Plants, Animals, Food and Feed (comitology).⁹⁶ Once approved, manufacturers can

⁸⁵ European Parliament, 'Report on the Proposal for a Regulation of the European Parliament and of the Council Concerning the Placing of Plant Protection Products on the Market FINAL A6-0359/2007', p 133.

⁸⁶ Ibid, p 110.

⁸⁷ Ibid, pp 16-17, 18-20, 47, 49, 50, 72-73, 77, 93, 99, 102, 108, 110-111; European Parliament, 'Recommendation for Second Reading on the Council Common Position for Adopting a Regulation of the European Parliament and of the Council on the Placing of Plant Protection Products on the Market A6-0444/2008', pp 68-69, 73, 86, 88-89, 96-97.

⁸⁸ Commission, 'Proposal for a Regulation', note 77 above, p 7.

⁸⁹ European Parliament, note 85 above, pp 15, 31-32, 72, 74, 78, 86, 132.

⁹⁰ PPPR, Arts 7(1) and 8(1), (2) and (4).

⁹¹ PPPR, Art 7(1).

⁹² PPPR, Art 10.

⁹³ PPPR, Art 11(1) and (2) second paragraph.

⁹⁴ PPPR, Art 12(1). The volume of public comments varies. A review of several recent applications for renewal of active substance approvals reveals that public comments are rare and rarer still in the case of applications for the approval of *new* active substances, if submitted at all. However, public comments on the application for renewal of approval of the highly controversial active substance glyphosate filled over 600 pages. Comments and responses are recorded in Peer Review Reports, available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?1>.

⁹⁵ PPPR, Art 12(2) second paragraph.

⁹⁶ PPPR, Art 13(1) and (2).

apply for authorisation to market the pesticide containing that approved active substance.⁹⁷ The Commission is required to maintain a publicly available list of approved active substances.⁹⁸

A recent study supporting the regulatory fitness (REFIT) evaluation of the Regulation examined the transparency of the active substance procedure. While it found that EFSA publishes a range of information, including summary dossiers, rapporteur draft assessment reports, reasoned opinions and conclusions on pesticides and member-lists and minutes of pesticides peer review expert meetings, the quality of this information has been criticised as being either too complex or too basic and uninformative.⁹⁹ With respect to public participation, although there is a 60 day consultation period, stakeholders faced challenges to contributing due to a lack of resources and the tight timeframes, NGOs regarded the opportunities for civil society involvement to be insufficient and over a third of stakeholders felt that their contributions were not valued.¹⁰⁰

Despite these criticisms, compared to pesticide authorisation (discussed below), this procedure is fairly transparent, in terms of public access to key documents and information and at least the existence of an opportunity for consultation. However, two recent events in particular led to proposals to change the EU level procedure: the 2017 European Citizens' Initiative (ECI) 'Stop Glyphosate',¹⁰¹ and a REFIT evaluation of the General Food Law.¹⁰² Their combined criticisms, foreshadowing the criticisms highlighted by the REFIT evaluation of the Regulation and largely supported by the European Parliament's ENVI Committee,¹⁰³ identified a lack of trust in EU regulatory decision-making stemming from the non-disclosure of data, the industry source of that data, reliance on unpublished studies and confidentiality requirements, in place to protect commercial interests.¹⁰⁴ The REFIT evaluation of the General Food Law found that civil society regarded many authorisation procedures in EU food legislation as lacking transparency and advised EFSA to 'adapt its way of working to the new expected levels of transparency' in order to protect its reputation.¹⁰⁵ The ECI demanded greater transparency specifically in the active substance approval procedure.¹⁰⁶

In response, the Commission committed to enhancing the transparency of the active substance approval procedure by adjusting the balance between disclosure of information and ensuring commercial confidentiality, where legitimate, through for example, increasing public access to studies contained in applications.¹⁰⁷ Its subsequent legislative proposal aims to enhance the transparency of EFSA's risk assessment procedures in the area of food law in order to increase its

⁹⁷ PPPR, Art 29(1)(a), see Part IV A.

⁹⁸ PPPR, Art 13(4).

⁹⁹ ECORYS, *Study supporting the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)* (EUR-OP, 2018), pp 165, 167-168; V Storck, DG Karpouzias and F Martin-Laurent, 'Towards a Better Pesticide Policy for the European Union' (2017) 575 *Science of The Total Environment* 1027, p 1030.

¹⁰⁰ ECORYS, note 99 above, pp 165, 168-170.

¹⁰¹ <http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002>.

¹⁰² Commission, 'The REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002) SWD(2018) 37 Final'.

¹⁰³ ENVI Committee, 'Draft Report on the Implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))' (2018).

¹⁰⁴ ECI, 'Annex to the European Citizens' Initiative: Ban Glyphosate' (undated) pp 1-2; European Parliament, 'MEPs Propose Glyphosate Phase-out, with Full Ban by End 2020' (19 October 2017) <http://www.europarl.europa.eu/news/en/press-room/20171019IPR86411/meps-propose-glyphosate-phase-out-with-full-ban-by-end-2020>; Commission, note 102 above, pp 35, 44.

¹⁰⁵ Commission, note 102 above, pp 44-45.

¹⁰⁶ ECI, note 104 above, p 2.

¹⁰⁷ Commission, 'Communication on the European Citizens' Initiative "Ban Glyphosate and Protect People and the Environment from Toxic Pesticides" C(2017) 8414 Final', pp 10-12.

legitimacy and public confidence in its work.¹⁰⁸ Proposed measures include making public scientific data and information contained in authorisation applications under EU food law as early as possible and providing for consultation of stakeholders to identify whether other relevant scientific data or studies are available, alongside stricter requirements with respect to the disclosure of information about EFSA's activities and a higher threshold for confidential treatment of information contained in applications.¹⁰⁹ Amendments proposed specifically to the Regulation ensure that the above proposed changes apply to active substance approval. Most notably, a new Article 10 requires EFSA to make public both dossiers submitted by applicants for approval, not just summary dossiers.¹¹⁰ Little changes with respect to pesticide authorisation, although the higher threshold for confidential treatment appears to apply.¹¹¹ However, how some of the proposed provisions will interact with current provisions on confidentiality is unclear.¹¹² On the whole, provisions explicitly enhancing transparency remain confined to active substance approval.

IV. TRANSPARENCY AND PESTICIDES REGULATION

A. Pesticide evaluation and authorisation

As mentioned, the Regulation divides EU Member States (and Norway) into Northern, Central and Southern zones.¹¹³ The aim is to improve efficiency,¹¹⁴ avoid duplication of work, reduce administrative burdens on industry and Member States, increase harmonisation and facilitate mutual recognition of authorisations.¹¹⁵ The authorisation procedure and communication and co-ordination between Member States are facilitated by three 'zonal steering committees', one for each zone, and an 'inter-zonal steering committee'. Neither zonal steering committees nor the inter-zonal steering committee is provided for in the Regulation. The zonal steering committees are chaired by participating Member States and meet every two months 'to discuss specific applications and issues arising which should be fed into' the inter-zonal steering committee.¹¹⁶

An applicant seeking authorisation must submit a 'draft Registration Report', which contains information and data on the risk assessment and risk management of the pesticide,¹¹⁷ to each Member State in which it intends to place the pesticide on the market.¹¹⁸ Evaluation of the application is conducted at 'zonal' level by the 'zonal rapporteur Member State' whose conclusions provide the basis for final, national authorisation decisions. To avoid duplication of work, other Member States in the same zone may not proceed with the file pending zonal rapporteur Member State evaluation.¹¹⁹ To facilitate efficient and swift operation of the zonal procedure, applicants

¹⁰⁸ Commission, 'Proposal for a Regulation of the European Parliament and of the Council on the Transparency and Sustainability of the EU Risk Assessment in the Food Chain COM(2018) 179 Final', pp 3, 8.

¹⁰⁹ Ibid, pp 18, 19, 26, 27-29.

¹¹⁰ Ibid, pp 40-42.

¹¹¹ Ibid, pp 41-42.

¹¹² See PPPR, Art 33(4) and *ibid*.

¹¹³ PPPR, Recital 29, Art 3(17), Annex I.

¹¹⁴ PPPR, Recital 25.

¹¹⁵ PPPR, Recital 29.

¹¹⁶ Commission, 'Guidance Document on Zonal Evaluation and Mutual Recognition under Regulation (EC) No 1107/2009 SANCO/13169/2010 Rev. 9', p 5.

¹¹⁷ Ibid, p 9; Commission, 'Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report SANCO/6895/2009 Rev 1'.

¹¹⁸ PPPR, Art 33.

¹¹⁹ Commission, note 116 above, p 4.

should request pre-submission meetings with their proposed zonal rapporteur Member State to enable discussion of the application, its potential problems, quality and strategy.¹²⁰

The zonal rapporteur Member State must make an independent, objective and transparent assessment of the application ‘in the light of current scientific and technical knowledge’ using available guidance documents and allowing other Member States in the same zone to submit comments for consideration in the assessment.¹²¹ In order to determine whether the pesticide meets the requirements established in Article 29 of the Regulation,¹²² it must apply the Uniform Principles.¹²³ The zonal rapporteur Member State must make its assessment available to the other Member States in the same zone (the ‘concerned Member States’) and allow an opportunity for comments.¹²⁴ The zonal rapporteur Member State may communicate with an applicant, for example to request additional information,¹²⁵ and should seek its comments on the zonal draft Registration Report.¹²⁶ The zonal rapporteur Member State produces a final assessment, in the form of a Registration Report, and decides whether to grant or refuse authorisation.¹²⁷ The concerned Member States must grant or refuse authorisations on the basis of the conclusions of the zonal rapporteur Member State.¹²⁸ Concerned Member States may still assess their own national requirements and impose appropriate conditions and ‘other risk mitigation measures’ in their own national authorisations.¹²⁹ In limited cases, a concerned Member State may refuse authorisation.¹³⁰

1. *The rules of the game*

The zonal evaluation and authorisation procedure operates differently in different Member States and zones, within the above framework. There are many examples but two suffice to illustrate here. Firstly, different Member States treat incomplete applications differently, with some rejecting such applications outright and requiring resubmission and others accepting submission of missing data. Secondly, some Member States treat the expert advice supplied to decision-makers on the risk assessments in applications as binding while others treat it as purely consultative.¹³¹ As discussed in Part II, transparency in the context of this regime requires clarity with respect to the rules governing the pesticide authorisation procedure in each Member State. Such clarity meets both the practical needs of applicants and the desires of any interested parties to understand the authorisation procedure, actors involved and how information in the application is used and assessed. In terms of the law, the Regulation imposes no obligation on Member States to publish information about their national authorisation procedures and requirements. In terms of national implementation, the level of information available in different Member States is highly variable. For example, the websites of some Member State CAs (such as the UK, the Netherlands, Germany and Belgium) contain comprehensive information on application and data requirements while at least one Member State

¹²⁰ Ibid, pp 7-8.

¹²¹ PPPR, Art 36(1) first paragraph.

¹²² PPPR, Art 36(1) second paragraph. See Part IV B.

¹²³ Regulation (EU) No 546/2011 [2011] OJ L155/127. The Uniform Principles establish a harmonised methodology and thresholds for assessing and determining the acceptability of risks posed by pesticides, SAM, *EU Authorisation Processes of Plant Protection Products - from a Scientific Point of View Scientific Opinion 5/2018* (EUR-OP, 2018), p 50.

¹²⁴ PPPR, Art 36(1) first and third paragraphs.

¹²⁵ PPPR, Art 37(1).

¹²⁶ Commission, note 116 above, p 13.

¹²⁷ Ibid, pp 13-14.

¹²⁸ Ibid, p 14.

¹²⁹ PPPR, Art 36(2) and (3).

¹³⁰ PPPR, Art 36(3) first and second paragraphs.

¹³¹ See Hamlyn, note 4 above, pp 53-79.

CA website publishes no information.¹³² Given the procedural differences between Member States, the rules by which their procedures operate cannot be assumed or guessed. The lack, or uneven availability, of information about the rules of the game impedes understanding of evaluation and authorisation procedures amongst interested parties, undermining transparency *per se* and perhaps too fulfilment of the requirements for transparency discussed in Parts IV A 2 and 3 below.

2. Access to information

Despite its potential drawbacks, as discussed in Part II, transparency requires access to information. Measures providing for access to information, for example, publishing decisions, the reasons for those decisions and their informational basis, and providing opportunities for interested parties to evaluate the knowledge used to justify those decisions may enhance accountability, increase trust in regulators and facilitate democratic control of discretionary decision-making.

The Regulation imposes no requirement on Member States to give reasons for their authorisation decisions, demonstrating a lack of ambition in the legislation in terms of ensuring transparency through access to information. Uniform Principle A.5 second paragraph requires Member States to ‘come to a reasoned decision within 12 months of receiving a technically complete dossier’ but omits a requirement for its publication.¹³³ The Regulation’s requirements on access to information provide some measure of transparency with respect to individual pesticides and the knowledge base for decisions. Article 57 obliges Member States to keep certain information electronically available to the public on pesticides authorised or withdrawn under the Regulation. Article 60(2) requires Member States to compile and make available on request, lists of test and study reports concerning individual pesticides and the substances they contain, including those for which the applicant claimed data protection under Article 59. The lists include information on whether the reports were ‘certified as compliant with the principles of good laboratory practice or of good experimental practice’,¹³⁴ enabling some scrutiny of the quality of the information used in decision-making.

Beyond the legal requirements in the Regulation, Commission guidance recommends publication of the final Registration Report ‘if legal provisions in the individual MS allow’, minus confidential information.¹³⁵ Registration Reports contain reasons for decisions and a Reporting Table recording unresolved differences of opinion on technical issues between the zonal rapporteur Member State and concerned Member State ‘for transparency reasons’.¹³⁶ Levels of publication of decisions among Member States vary. Some CAs publish all authorisation decisions while some publish most or only some. The French CA, for example, publishes the conclusions of its evaluation and part of the Registration Report for the purposes of transparency.¹³⁷ Some do not publish decisions to reject applications, perhaps due to classifying this information as commercially confidential. Very few Member States publish the information on which decisions are based or the Registration Reports, though they may be accessible through national legislation on access to information.¹³⁸ While mere guidance is unable to compel disclosure, Member States are discussing

¹³² Ibid, pp 90-91.

¹³³ Uniform Principles, note 123 above.

¹³⁴ PPPR, Art 60(3).

¹³⁵ Commission, note 116 above, p 14.

¹³⁶ Ibid, p 13.

¹³⁷ ANSES, *Press Kit: New missions for ANSES in the area of plant protection products, fertilisers and growing media* (2015), p 7.

¹³⁸ Hamlyn, note 4 above, pp 91-93.

publication of Registration Reports, indicating an appetite to enhance transparency through national implementation of norms found in guidance, despite the lack of legal requirements.¹³⁹

Furthermore, the content of Registration Reports suggests that at least some parts would be disclosable under Article 4(2) Directive (EC) 2003/4,¹⁴⁰ which provides that CAs may not refuse disclosure of ‘information on emissions into the environment’, unless one of the limited exceptions in paragraphs (b), (c) or (e) applies.¹⁴¹ The CJEU, in *Bayer*,¹⁴² endorsed a broad interpretation of ‘emissions ... into the environment, affecting or likely to affect’ the environment,¹⁴³ finding that it covered emissions of pesticides and the substances contained in them.¹⁴⁴ Although the CJEU limits information disclosable to that relating to actual or foreseeable emissions under ‘normal and realistic conditions of use’,¹⁴⁵ and despite remaining ambiguity,¹⁴⁶ this interpretation may mean large amounts of data and studies are disclosable, under the guidelines laid down by the CJEU for CAs, including importantly, information on the medium- to long-term consequences of emissions on the environment.¹⁴⁷ More recently, the CJEU extended this interpretation to similar provisions requiring EU institutions to disclose information which ‘relates to emissions into the environment’.¹⁴⁸ In these judgments, the CJEU explicitly recognises that the public require access to information relating to emissions into the environment to check whether the assessments on which CAs base their authorisation decisions are correct and to understand the effects of emissions on the environment, in order thereby, to review the justifications for those decisions.¹⁴⁹ Finally, these cases suggest the incremental spread of transparency illuminating the pesticides regulatory landscape; something which may continue in the future.

The increased availability of such information certainly has the potential to enhance transparency. However, simply disclosing information is often insufficient; the information itself must be ‘intelligible, clear and ultimately accountable’.¹⁵⁰ If Registration Reports are of poor quality or available solely in the national language, publication may provide only limited improvements in

¹³⁹ Ibid, p 92.

¹⁴⁰ Directive (EC) 2003/4, note 41 above. For examples of Registration Reports, see BVL’s (German CA) website: https://www.bvl.bund.de/EN/04_PlantProtectionProducts/01_ppp_tasks/02_ppp_AuthorisationReviewActSub/02_ppp_RegistrationReports/psm_RegReports_node.html.

¹⁴¹ These exceptions relate to the adverse effects of disclosure on ‘international relationship, public security or national defence’; ‘the course of justice’ for example ensuring fair trials or criminal investigations; and ‘intellectual property rights’.

¹⁴² *Bayer CropScience and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden*, C-442/14, EU:C:2016:890.

¹⁴³ Directive (EC) 2003/4, note 41 above, Art 2(1)(b).

¹⁴⁴ *Bayer*, EU:C:2016:890, paragraph 76. See also *Commission v Stichting Greenpeace Nederland and PAN Europe*, C-673/13 P, EU:C:2016:889, paragraph 75.

¹⁴⁵ *Bayer*, EU:C:2016:890, paragraphs 76-77, 81. See also *Stichting Greenpeace Nederland*, EU:C:2016:889, paragraphs 74-75.

¹⁴⁶ VA Buonsante and A Friel, ‘What Is Information Relating to Emissions into the Environment?’ (2017) 8 *European Journal of Risk Regulation* 453.

¹⁴⁷ *Bayer*, EU:C:2016:890, paragraphs 87–96.

¹⁴⁸ Regulation (EC) No 1049/2001 [2001] OJ L145/43, Art 4(2) first indent and Regulation (EC) No 1367/2006 [2006] OJ L264/13, Art 6(1); *Tweeddale v EFSA*, T-716/14, EU:T:2019:141, paragraphs 76-119, *Hautala and Others v EFSA*, T-329/17, EU:T:2019:142, paragraphs 83-122. As a result of this interpretation, EFSA was required to publicly release, in full, studies relating to the toxicity and carcinogenicity of glyphosate, *Tweeddale*, EU:T:2019:141, paragraphs 120-129, *Hautala*, EU:T:2019:142, paragraphs 123-125.

¹⁴⁹ *Tweeddale*, EU:T:2019:141, paragraph 91, *Hautala*, EU:T:2019:142, paragraph 98, *Stichting Greenpeace Nederland*, EU:C:2016:889, paragraph 80.

¹⁵⁰ OECD, *The Governance of Regulators’ Practices: Accountability, Transparency and Co-Ordination* (OECD, 2016), p 45.

transparency.¹⁵¹ Furthermore, the communication of information must be audience-sensitive to be effective.¹⁵² Even this is not straightforward; public communication activities that purport to disseminate factual information in the interests of transparency may instead seek to effect social control through manipulating public opinion and influencing behaviour.¹⁵³ Finally, the capacity of the recipient of the information to appraise and use that information matters. Transparency differs little from concealment in a society lacking ‘an active interpretive culture willing to criticise and able to make sense’ of the disclosed information.¹⁵⁴ In the highly specialised world of pesticides, review by any scientific expert may not be enough; the right expert is required, and even they must be sufficiently detached from the subject matter to ensure unbiased review.¹⁵⁵

Overall, the Regulation imposes no requirement on Member States to publish their assessments, decisions on authorisation and the reasons and information behind decisions. As *Bayer* and experience of EU level litigation over access to documents suggest,¹⁵⁶ even with rights established in legislation, access in practice may remain challenging. Finally, publishing decisions is a relatively unambitious form of accountability,¹⁵⁷ suggesting the importance of the openness of the entire decision-making process.¹⁵⁸

3. Public participation

Part II highlighted the link between wider participation in decision-making and enhanced transparency, and a consequential increase in accountability, trust in regulators and public support for decisions. Furthermore, in circumstances characterised by high levels of complexity and social and ecological uncertainty, engaging with a broad range of participants contributing different knowledge and values, may generate better decisions, aid identification of errors and help solve problems.

In terms of legal requirements, the Regulation contains no provision for public or stakeholder engagement during either the zonal evaluation or national authorisation procedures. With respect to the operation of national procedures, again, Member State practice varies, with some CAs consulting, for example, farmers and other pesticide users or other actors involved in plant protection.¹⁵⁹ Evidence suggests that few, if any, CAs consult wider industry, civil society organisations (CSOs) or publics. Indeed, Member States would not welcome wider participation due to, amongst other things, fear of NGO pressure and the influence of non-scientific opinions or public opinion in the decision-making process. Furthermore, despite provision, in the Regulation and guidance, of opportunities for contact between zonal rapporteur Member States and applicants during evaluation (discussed above), few zonal rapporteur Member States appear to maintain good channels of communication with applicants in practice.¹⁶⁰ That said, evidence also suggests that industry may have regular contact with CAs at national and zonal levels on matters other than specific applications, including procedural and scientific issues, for example interpretation and

¹⁵¹ Hamlyn, note 4 above, p 76.

¹⁵² O'Neill, note 42 above, pp 80-85; OECD, note 150 above, p 38.

¹⁵³ K Yeung, 'Government by Publicity Management: Sunlight or Spin?' (2005) *Public Law* 360.

¹⁵⁴ Jasanoff, note 48 above, pp 33-34.

¹⁵⁵ *Ibid*, p 34. Some of these concerns echo those expressed in relation to information disclosed with respect to active substances, discussed in Part III B.

¹⁵⁶ Lee, note 66 above, pp 198-199. See also *Tweeddale*, EU:T:2019:141 and *Hautala*, EU:T:2019:142.

¹⁵⁷ L Stirton and M Lodge, 'Transparency Mechanisms: Building Publicness into Public Services' (2001) 28(4) *Journal of Law and Society* 471, p 475.

¹⁵⁸ Lodge and Stirton, note 31 above, p 358.

¹⁵⁹ Hamlyn, note 4 above, pp 93-94.

¹⁶⁰ *Ibid*, pp 93-94.

implementation of the Regulation and interpretation of application and dossier requirements, and participation in annual open zonal steering committee meetings in the Central and Southern zones in which similar matters are discussed.¹⁶¹

B. Why improve transparency at pesticide authorisation?

Criteria for approving active substances and authorising pesticides are complex so some detail is necessarily excluded. Article 4(1) provides that an active substance 'shall be approved ... if it may be expected that [pesticides] containing that active substance meet the requirements provided for in paragraphs 2 and 3' of Article 4. Article 4(2) requires that the residues of the pesticide in question do not have 'any harmful effects on human health' or 'any unacceptable effect on the environment'. Article 4(3) requires, *inter alia*, that the pesticide be 'sufficiently effective' and that it has 'no immediate or delayed harmful effect on human health' and no unacceptable effects on plants, plant products or the environment. Article 4(5) provides that compliance with these requirements may be demonstrated by 'one or more representative uses of at least one' pesticide containing the relevant active substance. Active substances are assessed 'as if' they are in pesticides and 'having regard to realistic conditions of use'.¹⁶² However, the minimum requirement for one representative use of one pesticide confines assessment, perhaps necessarily, to a certain level of generality despite the likely diverse conditions of eventual use. By contrast, the requirements for authorisation of pesticides envisage an extended range of considerations, including exposure risks posed by its technical formulation, that the nature and quality of its ingredients (active substances, safeners, synergists and co-formulants), relevant impurities and residues can be determined and that its physical and chemical properties are acceptable for appropriate use and storage.¹⁶³ Context of use shines more strongly through these requirements. For example, under Article 29(3), compliance with many requirements must be assessed 'under agricultural, plant health and environmental conditions' relevant to the use of the pesticide in question and 'representative of the conditions prevailing in the [relevant] zone'. Finally, the interaction between the ingredients in the pesticide must be considered.¹⁶⁴

The considerations relevant to active substance approval and pesticide authorisation differ in nature, number and context-specificity and many emerge only at the authorisation stage. That active substance evaluation does not, and probably cannot (without lengthy delays), take into account use-, context- and final product-specific criteria militates towards increasing the transparency of the stage of decision-making at which they *are* considered; authorisation. EFSA has conceded that the distinction between active substances and pesticides may explain the difference between its conclusions on the carcinogenic potential of glyphosate, having assessed glyphosate alone, and those of the International Agency for Research on Cancer which also assessed glyphosate-based formulations.¹⁶⁵ Assessment against the conditions prevailing in the relevant zone, in particular, presents a reason for wider local/national engagement in decision-making through access to relevant information and participation. Such questions may become more pertinent when closer to the publics most likely to be affected by the decision and zonal evaluation and national authorisation represent the last opportunity for those publics and stakeholders to contribute national and culture-specific concerns, values and knowledge to decision-making. There is,

¹⁶¹ Ibid, p 94.

¹⁶² PPPR, Arts 4(2) and (3).

¹⁶³ PPPR, Art 29(1).

¹⁶⁴ PPPR, Art 29(6) second paragraph.

¹⁶⁵ Storck, Karpouzas and Martin-Laurent, note 99 above, p 1028; EFSA, 'Conclusion on the Peer Review of the Pesticide Risk Assessment of the Active Substance Glyphosate' (2015) 13(11) *EFSA Journal* 4302, p 11. See also *Hautala*, EU:T:2019:142.

furthermore, recognition in high-level EU policy circles, and elsewhere, that the transparency of pesticide authorisation requires improvement.¹⁶⁶

V. SHADES OF TRANSPARENCY AND CHIAROSCURO REGULATION

The above discussion suggests that the Regulation, overall, does not operate transparently. However, to enlighten our understanding of transparency in complex risk regulation regimes, this claim may be further nuanced. The meaning, benefits and limitations of transparency, and its implications, vary depending on context.¹⁶⁷ There are, furthermore, different degrees of transparency which influence its capacity to facilitate knowledge,¹⁶⁸ for example, the amount revealed, and the size and identity of the permitted audience. Transparency may move in different directions, illuminate either events or processes and occur in retrospect or real-time.¹⁶⁹ It may also manifest different forms at different times, levels of governance and depending on the purpose it serves.¹⁷⁰ The following discussion reinforces this understanding of transparency and elucidates additional areas of variation. Firstly, comparison between active substance approval and pesticide authorisation reveals that, even within a single regulatory regime or piece of legislation, levels of transparency can vary significantly depending on procedure and regulatory object (here, active substance or pesticide), notwithstanding the interdependence of both procedures and regulatory objects. Secondly, I highlight the almost infinitely variable levels of transparency accorded to different interested parties during pesticide authorisation.

I use the concept of 'chiaroscuro regulation' here to capture and describe certain characteristics of the regime and the nature of these variations in transparency. As discussed in Parts III B and IV A, these variations and characteristics stem from the legal requirements governing active substance approval and pesticide authorisation, their implementation – particularly national implementation of the pesticide authorisation procedure – and policy developments.¹⁷¹ Firstly, the concept seeks to highlight the dramatic contrasts in levels of transparency between different procedures, levels of governance, regulatory objects and, within pesticide authorisation, different CAs. Secondly, it illustrates the idea, with respect to audience, that the same regulatory object, procedure or CA may appear visible or illuminated from some angles or perspectives but invisible or obfuscated from other angles. Finally, it acknowledges the incremental and particular nature of developments in transparency. The Commission's proposal to improve the transparency of risk assessment in the food chain (see Part III B) and CJEU case law on transparency in pesticides regulation (see Part IV A 3), while marking positive steps, will not flood the entire regime with light. Though they may shift or recede, shadows remain where improvements in transparency focus only on specific areas or are approached from specific directions. These characteristics are elaborated further below. The analysis closes with a brief discussion of some of the potential consequences of chiaroscuro regulation.

A. Active substance approval vs pesticide authorisation

The Commission acknowledges that currently transparency and confidentiality rules vary depending on the sub-area of food law.¹⁷² However, the variations extend beyond the sub-areas into different

¹⁶⁶ SAM, note 123 above; Storck, Karpouzias and Martin-Laurent, note 99 above.

¹⁶⁷ Fisher, note 17 above, pp 277, 283.

¹⁶⁸ Schauer, note 67 above, p 1345.

¹⁶⁹ D Heald, 'Varieties of Transparency' in Hood and Heald, note 11 above.

¹⁷⁰ C Hood, 'Transparency in Historical Perspective' in Hood and Heald, note 11 above.

¹⁷¹ I am grateful to the editors/anonymous peer reviewer, for clarifying this point.

¹⁷² Commission, note 108 above, p 3.

procedures *within* the Regulation. As discussed in Part III B, though not ambitious, active substance approval enjoys some degree of transparency and garners the vast majority of current proposed transparency-related improvements. The determinants of issue salience are complex. However, the glyphosate and neonicotinoid (all active substances) controversies may constitute ‘focusing events’ which, combined with media attention, increase visibility and channel items onto the political agenda.¹⁷³ Occurrence at EU level and the high profile of EFSA and the Commission make active substance approval visible and perhaps therefore an obvious target for attention, despite its distance from EU citizens.

By contrast, pesticide authorisation offers little transparency although, as discussed in Part IV A, there is some variation between Member States. Potential reasons may include the lower profile of pesticides and lower visibility of national decision-making partly stemming from the absence of detail on the operation and institutions of the zonal system on the face of the legislation.¹⁷⁴ For example, the Regulation does not mention zonal steering committees. They are mentioned only in guidance,¹⁷⁵ which establishes a very loose framework for their operation and omits detailed norms pertaining to transparency, although part of their remit is to ensure transparency.¹⁷⁶

Regulatory regimes are not delimited by legal instruments but rather extend to ‘the norms, the mechanisms of decision making, and the network of actors ... involved in regulation’.¹⁷⁷ Risk regulation regimes, such as that examined here, consist in ‘the complex of institutional geography, rules, practice, and animating ideas that are associated with the regulation of a particular risk or hazard’, extending to ‘highly fragmented administration and complex overlapping systems controlling related aspects of a risk’.¹⁷⁸ Thus, in a decentred regime, the role of state law may diminish, ceding space to other forms and sources of norm-generation, for example guidance.¹⁷⁹ Vaughan has argued that a function of post-legislative guidance, such as that mentioning zonal steering committees, is to ‘extrapolate’ from the legal text where that text is silent. The aim is to fill a gap left by that silence where necessary to ensure operation of the legislation in question,¹⁸⁰ ie, the Regulation. Here, zonal steering committees themselves and the rules on their functioning are necessary for the zonal system to work.

Procedures for adopting soft post-legislative acts (such as guidance) may themselves lack transparency due to, *inter alia*, the absence of information about participating stakeholders, wider consultations and oversight by the Council, Parliament or comitology.¹⁸¹ Indeed, the Commission’s guidance document on zonal evaluation, which mentions zonal steering committees,¹⁸² discloses scant information as to its genesis. On the other hand, this is arguably a small price to pay if the

¹⁷³ A Spendzharova and E Versluis, ‘Issue Salience in the European Policy Process: What Impact on Transposition?’ (2013) 20 *Journal of European Public Policy* 1499, p 1503.

¹⁷⁴ A new governance phenomenon explored in more detail in G De Búrca and J Scott (eds), *Law and New Governance in the EU and the US* (Hart, 2006).

¹⁷⁵ Commission, note 116 above.

¹⁷⁶ *Ibid*, p 22.

¹⁷⁷ D Levi-Faur, ‘Regulation and Regulatory Governance’ in D Levi-Faur (ed), *Handbook on the Politics of Regulation* (Edward Elgar, 2011), p 13 and references therein.

¹⁷⁸ Hood, Rothstein and Baldwin, note 27 above, p 9.

¹⁷⁹ Scott, note 26 above.

¹⁸⁰ S Vaughan, *EU Chemicals Regulation: New Governance, Hybridity and REACH* (Edward Elgar Publishing, 2015).

¹⁸¹ L Senden, ‘Soft Post-Legislative Rulemaking: A Time for More Stringent Control’ (2013) 19(1) *European Law Journal* 57.

¹⁸² Commission, note 116 above.

guidance or rules enhance legal certainty or the effective operation of the regime.¹⁸³ However, there is evidence of industry influence, at a zonal level, on the development of zonal practice,¹⁸⁴ which may pose problems, as discussed further in Part V C. Furthermore, in addition to the manner of adoption, the arrangements instituted by guidance, once established, may remain adumbrated. Discovering the existence of, and information about, zonal steering committees requires effort and some initial knowledge of what one is searching for, itself hard to obtain. Once discovered, zonal steering committees are inaccessible. For example, the Central zonal steering committee publishes some information on matters such as meetings or evaluation procedures on CIRCABC – an EU online communication and information resource centre with some publicly available pages. However, users require a (free) account and locating relevant documents is not straightforward. Overall, pesticide authorisation remains in the shadows.

It is noticeable that active substance approval, which, compared to pesticide authorisation, is the more transparent procedure under the Regulation, attracts proposals for transparency-enhancing reforms. Risk regulation regimes have faced increasing, though not universal, pressures for more openness. Such pressures do not necessarily coincide with low initial levels of openness and vary in terms of responses to pressures and elements of the regime targeted for increased openness.¹⁸⁵ Here, it may be that the limited transparency of active substance approval acts as a baseline from which to demand more, whereas the obscurity of pesticide authorisation, particularly the zonal system, raises the question whether there is enough knowledge of it in the first place to provoke agitation for more.

B. Differential transparency in pesticide authorisation

Despite an overall lack of transparency in the pesticide authorisation procedure, there are occasional flashes of transparency from some CAs, benefiting certain audiences. Regarding applicants, the availability of pre-submission meetings and the communication between CAs and applicants, for example during evaluation, help clarify the rules of the game and enable greater access to the regulator's decision-making process. This suggests increased transparency, although the prevalence of these practices varies according to CA, as discussed in Part IV A 3.¹⁸⁶ Greater transparency to wider industry may also be indicated by the 'regular contact' with CAs at national and zonal level outside specific applications.¹⁸⁷ This suggests potential for some involvement by industry in the operation of the regime generally, including input into shaping its implementation and questions of interpretation. However, industry is not monolithic and these limited instances of transparency do not extend to every industry actor. The inaccessibility of original Registration Reports, for example, disadvantages the generic pesticide industry for whom they represent valuable guidance for putting together applications.¹⁸⁸

Citizens and CSOs, by contrast, tend to experience much lower levels of transparency. Given the lack (with a few exceptions) of clear information from CAs about national authorisation procedures, the challenges of accessing information and an absence of opportunities for wider public participation in decision-making, as discussed in Part IV A, the pesticide authorisation procedure is not transparent with respect to publics and wider civil society. PAN-Europe notes that a drawback of zonal authorisation is the variable practices of stakeholder representation and transparency amongst Member States, as opposed to the Commission's flawed, but 'fair' policy of

¹⁸³ Vaughan, note 180 above, pp 245-246.

¹⁸⁴ See Part IV A 3.

¹⁸⁵ Hood, Rothstein and Baldwin, note 27 above, pp 151-157, 169.

¹⁸⁶ See also Hamlyn, note 4 above, pp 93-94.

¹⁸⁷ See Part IV A 3.

¹⁸⁸ Hamlyn, note 4 above, p 93.

stakeholder representation and transparency. It also expresses concern regarding close relationships between Member States and industry while other stakeholders are kept at a distance.¹⁸⁹ CSOs have expressed a similar sentiment with respect to active substance approval where they believe industrial interests are favoured over the public interest.¹⁹⁰ As discussed above, a feature of the zonal system is its obscurity and distance from citizens/CSOs, of whom few may be aware of its existence or procedures and of whom many may not have the resources to discover more, let alone participate.

In sum, in the context of a highly complex, polycentric and decentred multi-actor regulatory regime, it is impossible to draw final conclusions identifying a single level of transparency which holds true for the entire regime, including its implementation by Member States, both now and in the future. There are contrasts in transparency, depending on the relevant procedure, and the shades of transparency, even within one procedure, are almost innumerable. Overall, transparency varies according to individual regulator practice, actor or audience, level of governance, regulatory procedure and regulatory object. Its evolution, furthermore, appears influenced by existing levels of transparency and the high profile (or otherwise) of the regulatory object, reflecting further the incremental, particular and contingent nature of developments in transparency. Even if, therefore, a decision is made at EU level which, as a supranational decision-making procedure, may arguably seem further removed from citizens than zonal or national levels, if it is controversial or already visible, drives to improve transparency may be stronger.

C. Consequences of chiaroscuro regulation

Transparency is not necessarily an unalloyed good. It may have unintended consequences and requires more than simply 'turning on the light'.¹⁹¹ Increasing transparency may jeopardise other important goals or values.¹⁹² There are, for example, arguments for secrecy or concealment and transparency may have to compete with other important social values which differ, depending on context.¹⁹³ Commercial confidentiality,¹⁹⁴ national security and the protection of personal data are all in tension with transparency.¹⁹⁵ So too, are other valued objects such as effectiveness, fairness and legitimacy as well as trust and accountability themselves.¹⁹⁶ Furthermore, non-disclosure may be valuable for promoting honesty and frankness.¹⁹⁷

However, despite its complexity, transparency, alongside 'openness', is now widely accepted as a principle of good governance. Some argue it is a general administrative law principle.¹⁹⁸ Others contend it is a general principle of EU law.¹⁹⁹ Similarly, 'openness', interpreted as communication about EU activity and decisions in 'accessible and understandable' language, is recognised by the

¹⁸⁹ PAN-Europe, 'Zonal authorisation' (undated) <https://www.pan-europe.info/eu-legislation/zonal-authorisation>.

¹⁹⁰ ECORYS, note 99 above, p 170.

¹⁹¹ Fisher, note 17 above, p 306.

¹⁹² C Hood, 'Beyond Exchanging First Principles? Some Closing Comments' in Hood and Heald, note 11 above, p 219.

¹⁹³ Jasanoff, note 48 above, p 22.

¹⁹⁴ See Parts III B and IV A 2.

¹⁹⁵ Jasanoff, note 48 above, p 22; Fisher, note 17 above, p 280; C Abbot and M Lee, 'Economic Actors in EU Environmental Law' (2015) *Yearbook of European Law* 1, p 23-24.

¹⁹⁶ D Heald, 'Transparency as an Instrumental Value' in Hood and Heald, note 11 above.

¹⁹⁷ Fisher, note 17 above, p 289.

¹⁹⁸ *Ibid*, p 312.

¹⁹⁹ Craig and De Búrca, note 40 above, pp 574-575; K Lenaerts, "'In the Union We Trust": Trust-Enhancing Principles of Community Law' (2004) 41 *Common Market Law Review* 317, p 321.

Commission as a principle of good governance.²⁰⁰ Although ‘there is no necessary or automatic link between transparency and other values’,²⁰¹ it has the potential to offer multiple benefits. As discussed above, it is regarded as key to ensuring greater public accountability. Furthermore, though arguable, it may increase public trust or confidence in a regulator and decision-making process. It is linked, in the eyes of many, including the EU, to trust and legitimacy.²⁰² For example, as a principle which facilitates citizen participation in decision-making, transparency is intended to ‘guarantee that the administration enjoys greater legitimacy and is more effective and more accountable to the citizen’.²⁰³ More specifically, there are good reasons for enhancing the transparency of pesticide evaluation and authorisation separate to the measures taken with respect to active substance approval.²⁰⁴

In its current form, the Regulation, particularly pesticide authorisation, is unable to reap such benefits. Furthermore, the potential for context-specific knowledge to enhance the quality of national decisions is lost in the absence of participatory opportunities. Transparency, *per se*, does not guarantee the quality of decisions. However, its absence deprives interested parties of the ability to judge.

More specifically, the uneven levels of transparency between the procedures for active substance approval and pesticide authorisation raises concerns. The Commission’s response to the ECI, while arguing that it had no basis for banning glyphosate, notes that Member States must still evaluate all authorisations for pesticides containing glyphosate and may themselves impose a ban or restrictions where warranted on evidence related to the particular circumstances in their territories.²⁰⁵ While technically true, this overlooks the real danger that post-active substance approval, subsequent pesticide evaluation and authorisation will disappear into the shadowy zonal system, unilluminated by any formal transparency mechanisms to support public scrutiny, contributions to or influence of decision-making. Citizens are entitled to know which pesticides are authorised in their territory and the reasons and data behind the specific, national decision. The European Parliament has described the existing system of access to information as ‘totally obstructive’,²⁰⁶ arguing that ‘the public should be entitled to access the information on the chemicals they are exposed to’.²⁰⁷ The EU’s Scientific Advice Mechanism (SAM) notes that there is ‘no complete single overview of which pesticides are authorised, including where they are authorised in the EU and for which uses, as well as their market penetration and actual use’.²⁰⁸ Ultimately, it is no less important, given the requirements for pesticide authorisation discussed in Part IV B, that national citizens are able to hold national regulators to account via transparency mechanisms and contribute to decision-making, than EU citizens are with respect to EU-level actors regulators and procedures.

Differential transparency between industry generally and civil society may also have consequences. Private, economic actors (applicants) provide the majority of the information on which authorisation decisions are based.²⁰⁹ Given the resources available to applicants and

²⁰⁰ Commission, note 54 above, p 10.

²⁰¹ Lee, note 66 above, p 197.

²⁰² For example, Declaration No 17 on the right of access to information, annexed to the Final Act of the Treaty on European Union [1992] OJ C191/101; Vos, note 16 above, p 129; Lenaerts, note 199 above, pp 318-324.

²⁰³ Lenaerts, note 199 above, pp 319–320.

²⁰⁴ See Part IV B.

²⁰⁵ Commission, note 107 above, p 9.

²⁰⁶ European Parliament, note 85 above, p 110.

²⁰⁷ Ibid, pp 19-20.

²⁰⁸ SAM, note 123 above, p 33.

²⁰⁹ PPPR, Art 33.

regulators respectively,²¹⁰ this is reasonable and may increase the cost effectiveness and efficiency of regulation.²¹¹ It is also arguably inappropriate to use public funds to facilitate pesticide commercialisation and thereby gains which ultimately accrue to private industry.²¹² Reliance on such sources does, however, raise concerns regarding information asymmetry and the potential for industry to frame or manipulate regulator perceptions through the supply of selective or biased information.²¹³ Likewise, contact between industry and CAs arguably improves the efficient operation of the zonal system, for example through early resolution of problems with applications (as policy intended – see Part IV A). However, industry itself is largely free from public oversight and norms militating towards openness or acting in the public interest, raising concerns regarding accountability (although alternative accountability mechanisms may operate).²¹⁴ Such collaboration may decrease the relational distance between regulator and industry, potentially increasing the risk of capture.

Transparency may respond to involvement by private, particularly economic, actors in regulation.²¹⁵ It can, for example, ensure the public knows who is involved in, and what they are contributing to, the regulatory process, granting opportunities for scrutiny and reducing information asymmetries,²¹⁶ again supporting accountability. Access to information, for example the content of pre-submission meetings,²¹⁷ may reduce the risk of capture and industry influence may decrease with increased participation by other interests.²¹⁸ Thus, transparency may facilitate democracy, enabling public control to counter corruption or regulatory capture.²¹⁹ The absence of such transparency mechanisms, and contingent accountability gains, compromises the ability of publics to counteract industry influence.

VI. CONCLUSION

The Regulation generally, and its provisions governing the authorisation of pesticides in the EU specifically, offer rich insights into transparency in the context of a highly complex, polycentric and decentred, multi-actor, transnational risk regulation regime. These insights are encapsulated in the notion of ‘chiaroscuro regulation,’ which describes the myriad, and sharply contrasting, variations in transparency, shaded according to actor or audience, level of governance, regulatory object, Member State practice, regulatory procedure and perhaps still other factors yet to be demystified. There is no drawing of universal conclusions about levels of transparency, even within a single regime or piece of legislation. Furthermore, drives to enhance transparency, for example Commission policy on food safety regulation including active substance approval, evidence from the

²¹⁰ Lee, note 63 above, p 78.

²¹¹ Abbot and Lee, note 195 above, p 10.

²¹² Commission, note 107 above, p 11.

²¹³ BM Mitnick, *The Political Economy of Regulation: Creating, Designing, and Removing Regulatory Forms* (Columbia University Press, 1980), pp 209-211; MP Ferretti, ‘Why Public Participation in Risk Regulation? The Case of Authorizing GMO Products in the European Union’ (2007) 16 *Science as Culture* 377, p 385.

²¹⁴ J Freeman, ‘Private Parties, Public Function and the Real Democracy Problem in the New Administrative State’ in D Dyzenhaus (ed), *Recrafting the Rule of Law: The Limits of Legal Order* (Hart, 1999); B Morgan and K Yeung, *An Introduction to Law and Regulation: Text and Materials* (Cambridge University Press, 2007), p 281.

²¹⁵ Abbot and Lee, note 195 above, pp 21-24; Fisher, note 17 above, pp 312-313.

²¹⁶ Abbot and Lee, note 195 above, p 21; R Gönenç, M Maher and G Nicoletti, ‘The Implementation and the Effects of Regulatory Reform’ (2000) *OECD Economics Department Working Papers* 251, p 44.

²¹⁷ As suggested by SAM, note 123 above, p 39.

²¹⁸ S Webb Yackee, ‘Reconsidering Agency Capture during Regulatory Policymaking’ in DP Carpenter and DA Moss (eds), *Preventing Regulatory Capture: Special Interest Influence and how to Limit it* (Cambridge University Press, 2014) and references therein.

²¹⁹ Schauer, note 67 above, pp 1348–1349.

recent REFIT evaluation of the Regulation, the CJEU's decision in *Bayer* and other recent case law,²²⁰ and Member States' own discussions on access to information, reveal the potential for future change.²²¹ As such, conclusions drawn now about levels of transparency in the Regulation are not fixed, indicating the diversity of drivers of transparency and the evolution of transparency through time. Recent developments also suggest that change is contingent, as well as gradual and partial, leaving elements of the Regulation in the dark. Given the drawbacks of transparency, discussed above, some remaining darkness may arguably be desirable. However, the inumbration of certain elements of the regime, characteristic of chiaroscuro regulation, undermines enjoyment of the potential benefits of transparency. Uneven or diminished clarity regarding procedural rules and access to information at different levels of governance or with respect to different procedures or regulators reduces opportunities for public involvement and scrutiny. Differential transparency, depending on actor (put crudely, industry or civil society), weakens opportunities to counter-balance influence from a particular quarter, in this case, industry. These combine to reduce the potential for democratic accountability, better decisions or for a polity to make that judgment.

²²⁰ *Tweedale*, EU:T:2019:141 and *Hautala*, EU:T:2019:142.

²²¹ See Parts III B and IV A 2.